PROTOCOL

Evaluating the effectiveness and acceptability of free door to door transport to increase the uptake of breast screening appointments in Yorkshire: A cluster randomised GP feasibility trial

(DOORSTEP)

FULL PROTOCOL TITLE	Evaluating the effectiveness and acceptability of free door to door transport to increase the uptake of breast screening appointments in Yorkshire: A cluster randomised GP feasibility trial Picture (DOORSTEP)
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Protocol amendments since Version XX

State "none" if no amendments			
List amendments made since the last REC approved version	Version number	Date	Provide reason for the amendment State which sections of the protocol were replaced, added or deleted

GLOSSARY OF ABBREVIATIONS

BSS	Breast Screening Service
CEAC	Cost-effectiveness acceptability curves
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRN	Clinical Research Network
DARS	Data Access Request Service
DPIA	Data Protection Impact Assessment
EDC	Electronic Data Capture
ERY	East Riding of Yorkshire
eTMF	Electronic trial master file
EU	European Union
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HEY	Humber & East Yorkshire
HHTU	Hull Health Trials Unit
HIPAA	Health Insurance Portability and Accountability Act
HRA	Health Research Authority
HYMS	Hull York Medical School
ICC	Intraclass Coefficient
ICER	Incremental cost-effectiveness ratio
ICF	Informed Consent Form
ICMJE	International Committee of Medical Journal Editors
ID	Identification Code
ISF	Investigator Site File
ISO	International Organization for Standardization
ISRCTN	International Standard Randomised Controlled Trial Number
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHSBSP	NHS Breast Screening Programme
NICE	National Institute for Health and Care Excellence
non-CTIMP	non-Clinical Trials of Investigational Medicinal Products
NRES	National Research Ethics Service
PI	Principal Investigator
PIS	Participant Information Sheet
QALY	Quality adjusted life years
R&D	Research and Development
RCC	REDCap Cloud
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RGF	NHS Research Governance Framework
SOC	System and Organization Control
SOP	Standard Operating Procedure
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom

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TRIAL SUMMARY

Breast cancer is the most commonly diagnosed cancer in women in Yorkshire, causing more than 800 deaths per year in the region. Breast screening is one of the key tools to help diagnose breast cancer at an early stage and improve survival rates. Across Yorkshire, in the three years up to 2019/20 an average of 28.6% of invited women had not attended their appointment. Among the non-attenders, a major reason was the difficulty in travelling to the appointment. This study will assess whether offering free, bookable, door-to-door transport to and from breast cancer screening appointments could increase the number of women attending screening.

We will compare two groups. Women registered at GPs in group one will receive information about booking free transport alongside their breast screening invitation. Women registered at GPs in group two will receive the breast screening invitation as normal with no additional offer of transport. Permission to use data collected by the Breast Screening Service on women invited for a breast screening appointment will be obtained. We expect that providing free transport will increase the overall screening rates, resulting in earlier breast cancer diagnosis and improved survival rates. The findings from this study will inform a larger study.

1. PROTOCOL INTRODUCTION

Breast cancer is the most commonly diagnosed cancer for women across Yorkshire with around 4,300 women diagnosed each year(1). Breast cancer survival rates are highly associated with stage at diagnosis: five-year survival for women diagnosed at Stage I is 97.9%; at stage IV, it is 26% (2). The NHS breast screening programme started as a tool to ensure that more breast cancers were diagnosed at earlier stages(3). Whilst all eligible women between the ages of 50 and 70 are invited to a breast screening appointment (on a three-yearly schedule), in Yorkshire only 71.4% attended their appointment(4). On average in England 8.4 breast cancers are diagnosed for every 1000 women screened(5). With approximately 197,000 women not attending in Yorkshire over three years this translates to a potential 1,655 breast cancer cases that could have been diagnosed earlier through the screening service if the screening appointment had been attended (4). Public Health England recommends that 70% of women attending a

screening appointment is an acceptable threshold, but that 80% is achievable(6). Currently Yorkshire is significantly below this achievable threshold and there is substantial variation in attendance rates across the region.

Reasons for women not attending screening appointments include; not feeling at risk, previous negative experiences, language barriers, embarrassment or difficulties getting there(7-9). One of the most common barriers is difficulty in accessing the screening facilities either directly (e.g. due to the cost of transport) or indirectly (e.g. having other time commitments). A number of studies have identified that living further from a breast screening site is associated with being less likely to attend(10, 11). One possible approach for increasing screening uptake rates is to target interventions that ensure women can get to breast screening facilities "…at reasonable cost, in reasonable time and with reasonable ease"(12)(p6). The introduction of mobile breast screening vans targeted reducing the distance needed to travel by bringing breast screening facilities to local communities(10). However, constraints on where they can be located due to the van size, need for access to electricity and parking for operational staff and attendees have resulted in them not always being located in sites that are easy to get to without a car, or are based in areas unfamiliar to the women who need to attend(7). Additional measures such as providing transport to reduce the physical barrier between home and screening site are still needed to allow some women to attend their appointment.

Providing free door-to-door transport to get people to healthcare appointments for those who would otherwise find it difficult is not a new idea. The Yorkshire Ambulance Service carries out around a million non-emergency journeys each year transporting patients to hospital appointments(13). Women attending a routine breast screening appointment are not eligible to access this free transport service(14). A number of studies have investigated interventions to target improving access to screening appointments including providing taxis, bus passes and transport vouchers (15-17). To increase the uptake of breast screening in inner city Cardiff, Bell et al. (17) provided women in three GP practices with a package of measures that included the offer of transport to the screening centre. The intervention resulted in an 15% increase in attendance at screening compared to the previous screening rate for these GP practices. However, as this was not an RCT there was no control group and the transport offer was

part of a package of measures, so the direct impact on attendance was not assessed. We hypothesise that offering a free, easily accessible door-to-door transport service will improve breast screening rates in Yorkshire. We are proposing this feasibility trial as there is currently a lack of robust evidence to support the commissioning of this service for attendance at screening.

2. AIMS AND OBJECTIVES

We will conduct a GP cluster randomised controlled feasibility trial to compare providing participants with a free bookable door-to-door transport service alongside the routine breast screening invitation letter with a control arm that will only receive the routine breast screening invitation letter. This is an essential first step to understanding the feasibility of the trial procedures and intervention delivery and will give us a signal of efficacy, estimate of cost effectiveness and provide data to inform sample size calculations for a future definitive phase III randomized controlled trial. We will collect routine screening attendance data from the NHS Breast Screening Programme (NHSBSP), and also collect the deprivation scores for the residential locations and participants' ethnicity data from NHS England (through the Data Access Request Service (DARS) process). In addition, we will assess how women have travelled to the screening sites using travel surveys for study participants in the control and intervention arms. We will interview a sample of women from the intervention arm and transport providers to assess levels of acceptability for the intervention.

3. TRIAL DESIGN

The intervention is the offer of free door-to-door transport to a routine breast screening appointment for all eligible women registered at GP practices randomised to the intervention arm of the trial. All women registered with GP practices in the intervention arm will be given information on how to book transport to their appointment. The information will be delivered through a letter (detailing the offer) that is included at the same time as the screening invite letter sent by the Humberside Breast Screening Service (BSS). The transport offer will include being driven from home (or workplace) to the appointment, the driver will wait for the appointment to finish (around 15 minutes) and

drive the participant back. We are working with taxi companies based in the two areas of East Riding of Yorkshire (ERY) and Kingston-Upon-Hull (Hull). The transport provider will provide transportation services, including any drivers licensed to carry out private hire bookings in accordance with the Private Hire Vehicle Regulations. The transport providers will be finalised when we know which GP practices have been recruited to the trial, as they cover specific areas. The trial will cover the costs of the journeys.

The free transport will be offered with the first HEY screening invitation letter sent to the women. If the women didn't attend the first appointment offered, then a second invitation will be sent routinely from the screening service, and free transport will be offered at this stage again. If the women don't attend the second appointment offered by the HEY screening service, then no further appointment will be sent by screening service. The women can then use the free transport up to 6 months from the first invitation letter if they subsequently book the screening appointment themselves.

If any of the participants in the intervention arm need a technical recall or recall for further assessment a free transport will be offered by the Doorstep study for these appointments. Sometimes the further assessment may take longer and in this case the taxi driver will not wait at the centre. However, a return taxi will be booked in a timely manner.

The study is a cluster randomised feasibility trial, with clustering at the level of the GP practice. We will recruit 8 GP practices to this study. GPs will be allocated to the intervention group or the control group. The flow of participants is shown in Figure 1. A GP cluster randomised design has been proposed instead of individual patient level randomisation for two reasons: the complexity of individual randomisation and preparation of letters with/without transport information for the screening service; and the letter inviting women to book transport may be shared or discussed between women who are registered at the same practice or live in the same area leading to trial contamination. Known issues of requiring larger sample sizes and recruitment bias in cluster RCTs are mitigated as all women at intervention practices will receive the intervention letter and anonymised routinely collected outcome data is being obtained (18).

Women at participating GP practices will receive the standard screening invitation letter at the usual planned time from the screening service with women registered at an intervention GP practice receiving additional information about the transport booking instructions. A participant notification poster will be displayed at GP practices during the trial.

We estimated 8000 participants will be included in total based on the number of eligible women (between ages 50-70) at eight average sized GP practices. The sample size of eight practices will allow for the reliable estimation of key feasibility figures and detection of signal of efficacy for the future full trial(19).

3.1 OUTCOME MEASURES

This study is a feasibility trial with primary outcome measures designed to assess the feasibility of conducting a future definitive RCT. The primary and secondary outcome measures are described next.

3.1.1 PRIMARY OUTCOMES

As a feasibility trial, the primary aim is to assess the feasibility of conducting the future definitive RCT. The primary feasibility outcomes are summarised in Table 1 along with criteria that will be used as a guide for progression to a future definitive phase III trial and described here:

1. Number of GP practices that agreed to participate and were randomised ahead of the scheduled breast screening invitation window.
2. Percentage of women invited from GP practices located in the 10% most deprived areas.
3. Percentage of intervention invites sent out by the BSS to all women during the scheduled breast screening invitation window.
4. Percentage of women who requested transport who were transported to and from their appointment by the service.
5. Acceptability of the intervention to the women and the service providers.
6. Completion and transfer of the screening and transport service data when required for analysis.

Table 1 Primary Outcomes to assess feasibility and progression criteria

Feasibility Outcomes	Outcome Measure	Green	Amber	Red
Recruitment and randomisation of GP practices	Number of GP practices that agreed to participate and were randomised ahead of the scheduled breast screening invitation window.	8 (planned number of practices)	6-7 (numbers may still be achieved if invitations sent during part of the period, or less practices with more women)	<6 (insufficient number of practices/women included to provide data for sample size and feasibility estimates)
	Percentage of women invited from GP practices located in the 10% most deprived areas.	30%	15-30%	<15%
Fidelity of the transport intervention	Percentage of intervention invites sent out by the BSS to all women during the scheduled breast screening intervention window.	100% (all 4 intervention sites)	75%	<75%
Fulfilment of requests for the transport intervention	Percentage of women who requested transport who were transported to and from their appointment by the service.	100%	50-99% (explore reasons such as too many appts same date/time)	<50% (not viable to increase or change transport service to meet the demand)
Acceptability of the intervention to the women/service providers	Qualitative interviews	Acceptable to all interviewed and no major barriers identified.	Acceptable with some modifications	Not acceptable to majority of people interviewed
Completion and transfer of screening and transport service data when required for analysis	Screening service attendance data	Screening data provided for all women in both arms of the trial	Partial data provided	Data has not been transferred
	Transport Providers	Transport service data provided for all trips in the intervention arm of the trial	Partial data provided	Data has not been transferred

3.1.2 SECONDARY OUTCOMES

The secondary outcomes are summarised below and are the intended outcomes for the definitive trial, and the data that will help inform sample size calculations for the phase III trial.

1. Screening uptake rates– percentage attendance at screening appointments, exploring if there is a signal of efficacy (increase in screening rates in the transport intervention arm compared to usual care).
2. Transport Intervention uptake rates.
3. Cost-effectiveness – reporting estimates of cost-effectiveness of the transport intervention.

3.2 RECRUITMENT PROCESS

We will recruit eight GP practices from the East Riding of Yorkshire (ERY) and Kingston-Upon-Hull (Hull) identified with the support of the local CRN and the Humberside Breast Screening Service (BSS). The schedule for inviting women from GP practices is determined three years in advance, running on a 3-yearly rota. We will recruit GP practices whose registered women are scheduled to be invited in the 12-month intervention phase of the study. All women invited for a routine breast screening appointment who are registered at these eight practices will be included in the trial. The Humberside BSS has one permanent screening site at Castle Hill Hospital and two mobile vans that serve ERY and Hull. Women are invited to attend the nearest site to their home postcode, but some may opt to attend the Castle Hill permanent site.

3.2.1 INTERVENTION ARM

Women registered at an intervention GP practice will receive the standard screening invitation letter at the usual planned time from the screening service with additional information about the transport booking instructions. All women in the intervention arm who attend the screening appointment will be asked to complete an intervention travel survey when they attend. Thirty women in the intervention arm will be recruited for qualitative interviews.

3.2.2 CONTROL ARM

Women at participating GP practices will receive the standard screening invitation letter at the usual planned time from the screening service. Women in the control arm

that are attending their appointment will also be asked to complete a control arm travel survey when they attend their screening appointment.

3.2.3 ELIGIBILITY

Inclusion criteria:

- GPs located in East Riding of Yorkshire or Kingston Upon Hull.
- Whose women meet the age criteria for the national breast screening programme (between 50 – 70 years old) and are due to be invited to attend a routine screening appointment during the intervention window.

Exclusion criteria:

- GP practices located outside of the set geographical area
- Women with Non-routine screening appointments

3.2.4 INFORMED CONSENT

Eight GP practices that meet the eligibility criteria will be recruited for the trial through the CRN. All women invited for a routine screening appointment at the GP practices randomised in the intervention arm will receive information about how to book transport for their appointment alongside their screening appointment letter.

All women who attend their screening appointment will be offered the opportunity to complete a travel survey. There will be two travel surveys, one for the intervention arm and one for the control arm. As part of this travel survey women in the intervention arm will be asked whether they would be interested in being interviewed. If interested they will be able to include their contact details as part of the survey. From this list we will interview 20 women who attended their screening appointment and either travelled using the door-to-door transport service or travelled to the appointment without using this service. A participant information sheet with contact details of the researcher and or other local team members will be provided. Informed consent will be obtained following discussion of the study with the volunteer participants before starting the interview.

We are also aiming to interview 10 women who were in the intervention arm, but did not attend their appointment. These women will be contacted through the screening service. A participant information sheet with contact details of the researcher and or other local team members will be provided. Informed consent will be obtained following discussion of the study with the volunteer participants before starting the interview.

In addition, we are aiming to interview 10 of the transport providers. We will contact the transport providers through their taxi companies. They will be asked whether they are willing to take part and will be provided with a participant information sheet and required to complete a consent form before being interviewed.

After receiving the PIS at least a day will be given for the volunteer participant to make the decision on whether to take part in the interview or not.

We have included in the trial a budget for translators so that language is not a barrier to taking part in the interviews. The University of Hull has pre-existing links with translators who can be commissioned to translate for studies where individuals are being interviewed where English is not their first language.

4. RANDOMISATION

The study is a cluster randomised feasibility trial, with clustering at the level of GP practice. GP practices will be randomised 1:1 to the intervention arm or control arm with variable block sizes, stratified by area deprivation. A summary is provided in Figure 1.

Randomisation will be completed via the REDCap Cloud (RCC) online system provided by the HHTU. Full details of the randomisation scheme is not included in the study protocol as knowledge of these details might undermine randomisation by facilitating deciphering of the allocation sequence. Instead, this specific information will be provided in a separate randomisation strategy document with restricted access.

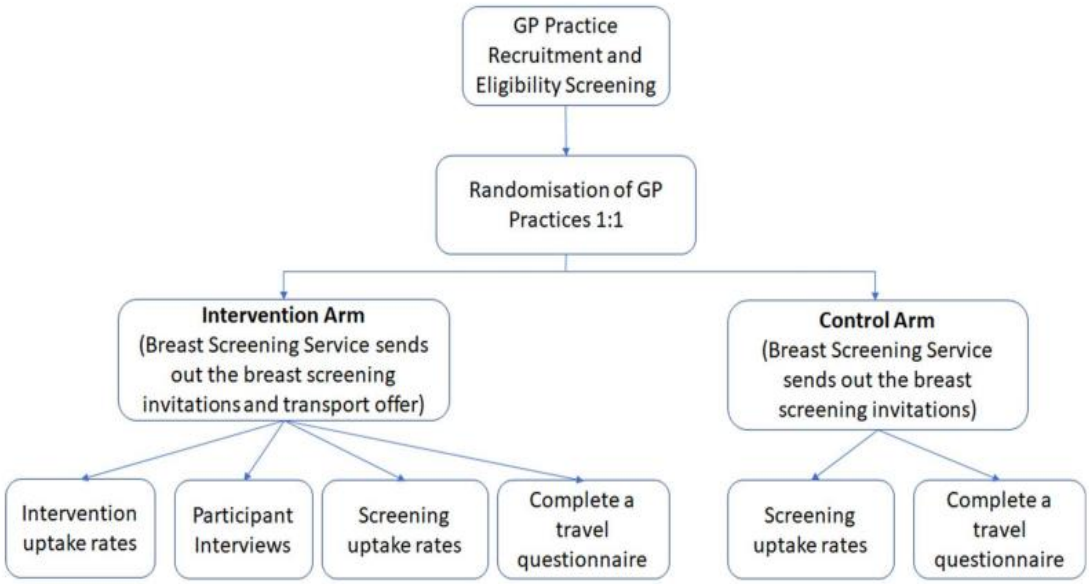

Figure 1 Recruitment randomisation and participant flows

4.1 METHOD OF IMPLEMENTING THE ALLOCATION SEQUENCE

Once a site is permitted to proceed with randomisation, authorised study staff with delegated responsibility for randomisation will follow the instructions in the latest study REDCap Cloud (RCC) User Manual, held in the Investigator Site File. This will involve logging onto the secure online randomisation system (RCC) administered by HHTU. RCC user accounts will be set up for delegated site staff by HHTU once all the necessary study documentation and approvals have been received. Randomisation will not be activated until the sponsor green light approval has been confirmed. HHTU will receive an alert with confirmation of the GP practice randomisation.

5. DATA COLLECTION

The data collection and analysis methods are summarized in Table 2 and described in full below.

Breast Screening Uptake Rates. This feasibility trial will be using data from the NHS Breast Screening Programme to calculate the breast screening uptake rates for each of the GP practices. The NHS BSP collect information on the age profiles of women who are invited for breast screening and document who attends and who does not in the six months following the initial routine invitation. The NHS BSP do not collect information on deprivation or ethnicity. We are applying for Section 251 approval to allow Humber and East Yorkshire BSS to transfer breast screening attendance data to NHS England (through the DARS process) and for NHS England to link this data with the index of multiple deprivation scores for the residential locations and ethnicity data. This data will then be transferred with patient identifiers removed to the study team at the University of Hull and analysed in the University of Hull data safe haven. We have developed a participant notification poster that will be displayed at participating GP practices throughout the trial to notify patients about the study and data linkage. A link will be provided to give them the option to opt out through NHS England. NHS England will remove patient's data from the dataset for those who have opted out of their data being used for research purposes.

Transport Intervention Uptake Rates. This feasibility trial will use data collected by the transport providers on trips provided to the screening service. The transport providers will be required to invoice the University for the cost of these journeys and will document number of trips and duration (time). This cost per trip is an integral part of the costs that will be used in the cost effectiveness analysis. In addition, all women will be asked to complete the travel survey which has been designed to collect information on transport uptake.

Cost effectiveness. Data collected on the costs of the journeys to the screening service and number of women attending their routine breast screening appointment will be used to calculate the cost per woman screened. A health economic model populated with data from the trial, systematic and targeted literature searches, and consultations

with clinical experts, patient representatives and the screening service will be developed to explore the impact of the intervention. Value of information analysis will be undertaken to make recommendations for the phase III trial. The trial will use the data to calculate equity impacts to identify potential distributional impacts on costs and benefits by measures of deprivation.

Acceptability of the intervention to the women. This feasibility trial will interview women who attended and those who did not attend their screening appointments. Those who attended their screening appointments will be recruited through the survey, where they will have the opportunity to say that they would be willing to be contacted by the study team for the interview. If they are willing to be interviewed they will be sent the participant information sheet and consent form to complete. The HEY Screening team will contact women who did not attend (within the 6 months window) and ask whether they would be willing to be interviewed. If they are willing they will be sent the participant information sheet and consent form to complete prior to the interview.

Acceptability of the intervention to the providers. We will be recruiting drivers and transport provider managers to interview them about their views on the acceptability of the intervention. Prior to the interview they will be given the participant information sheet and consent form to complete.

Table 2. Data Collection and Analysis

Outcome to be addressed	Analysis Method	Data Source
Breast Screening uptake rates	• Descriptive statistics – Number of women invited vs attended in the intervention and control arms. Sub group analysis by key characteristics (e.g. ethnicity, deprivation) • Intraclass coefficient (ICC) to inform the sample size (power calculation) for the definitive RCT	National routine breast screening data collected accessed through the NHSBSP. Transferred to NHS England to be linked with deprivation and Ethnicity data.
Transport Intervention uptake rates	• Descriptive statistics – Number of women who took up the offer of free door-to-door transport as a proportion of the total women in the intervention arm	Trips provided by transport providers. Travel questionnaires completed by women attending their screening appointment

Cost Effectiveness	• Economic evaluation to determine the cost of the intervention per woman screened • Health economic model to explore the impact of the intervention • Value of information analysis to make recommendations for the phase III trial • Equity impacts to identify potential distributional impacts on costs and benefits by measures of deprivation	Data collected by the trial including return trip costs. Systematic and targeted literature searches Consultation with clinical experts, patient representatives and the screening service
Acceptability of the intervention to women invited for the breast screening appointment	• Interviews to explore the acceptability of the intervention to the women invited for breast screening • Theoretically underpinned by the theoretical framework of acceptability (21) and analysed using thematic analysis (22)	Up to 30 interviews with women in the intervention arm. 10 who attended their screening appointment, but did not take up the offer of free transport, 10 women who did take up the free transport offer and 10 who neither attended or took up the transport offer.
Acceptability of the intervention to the transport providers	• Interviews to explore the acceptability of the service provided • Theoretically underpinned by the theoretical framework of acceptability (21) and analysed using thematic analysis (22)	5-10 interviews with the transport intervention providers

5.1 DATA COLLECTION METHODS

HHTU will develop the study database and data processes in accordance with HHTU SOPs.

HHTU data systems are within scope of the HHTU NHS Data Security and Protection Toolkit (Organisation Code - EE133824-HHTU).

Routine screening attendance data from the NHS Breast Screening Programme (NHSBSP) will be collected to evaluate screening uptake rates. We will apply for section 251 approval to allow the HEY Screening service to transfer NHS BSP data to NHS England and then NHS England to link this with data held nationally on the index of multiple deprivation and ethnicity. NHS England would remove all patient identifiers and data from any patients who have 'opted out' and transfer the data to the University of Hull Data Safe Haven for analysis.

To assess how women have travelled to the screening sites two travel surveys will be used, one for women in the intervention arm and one for women in the control arm.

A sample of women from the intervention arm and transport providers will be interviewed to assess levels of acceptability for the intervention.

Participants' interview recordings and transcriptions will be stored securely on HHTU/University of Hull Box. BOX is a collaborative cloud storage with the HHTU instance administered solely by HHTU staff. The HHTU Box instance uses only EU hosted servers. Box is ISO27001/ISO27018 certified, HIPAA compliant and holds SOC 1,2 and 3 reports. Data is encrypted at rest and in transit. Under GDPR, BOX act as a data processor on behalf of the University of Hull who is the data controller for HHTU projects.

Note: The site will maintain essential documentation in an Investigator Site File (ISF)

Note: Researchers are responsible for redacting personal identifiers prior to sending forms to HHTU Note: Describe what trial pseudo anonymised identifiers will be used on documentation

Note: Where full names are used, justify and describe how name will be used in the PIS and ICF.

The HHTU will adopt all reasonable measures to record data in accordance with the protocol. Under practical working conditions, some minor variations may occur due to circumstances beyond the control of HHTU. All protocol deviations will be documented with a reason. Where appropriate, deviations will be detailed in the published report.

6. TRIAL DATA MONITORING PLAN

A risk-based approach to monitoring will be adopted for the DOORSTEP study. A HHTU Study Monitoring Plan will be developed and agreed by the sponsor, CI and Trial Management Group (TMG). A Data Monitoring Plan will be agreed by the sponsor, CI and statistician to provide detailed instructions and guidance relevant to database set up, data entry, validation, review, query generation and resolution, quality control processes involving data access and transfer of data to the sponsor at the end of the study and archiving.

The HHTU will maintain contact with the Investigator(s) and designated staff by email or telephone during the study.

All the information obtained about participants in the course of the study is confidential and will be held in accordance with the General Data Protection Regulation (GDPR 2018). Data will be monitored for quality and completeness by the HHTU. Missing data will be chased until it is received or confirmed as unavailable.

7. TRIAL MANAGEMENT

7.1 RESEARCH GOVERNANCE

The study is funded by Yorkshire Cancer Research. The University of Hull is the sponsor of the study.

7.2 DAY-TO-DAY TRIAL MANAGEMENT

The day-to-day management will be conducted by the CI and personnel from HHTU. This will include a trial manager, a data manager and a trial administrator with oversight provided by members of the HHTU senior management team. Further oversight from senior members of the research teams will be provided as needed. All activities will be performed according to the relevant HHTU standard operating procedures.

7.3 TRIAL MANAGEMENT GROUP AND TRIAL STEERING OVERSIGHT COMMITTEES

The Trial Management Group (TMG) is comprised of the CI, HHTU team, key external members of staff assigned responsibility for trial management including protocol development, trial set-up, data analysis, obtaining regulatory approvals, submitting contracts, completing cost estimates, facilitating TSC meetings, monitoring compliance to recruitment, travel surveys & qualitative intervention, auditing consent procedures, data collection, data validation, database development and trial promotion and publication of trial results.

The Trial Steering Committee (TSC) is comprised of an Independent Chair, not less than two other independent members and a consumer representative. The Committee will meet approximately every 6 months. The Terms of Reference of the Trial Steering Committee are as follows:

• To provide overall supervision of the study, ensuring adherence to protocol
• To review developments during the study and recommend appropriate action
• To ensure that the rights and well-being of study participants is safeguarded and prioritised
• To review at regular intervals relevant information from other sources (e.g. other related studies), and recommend appropriate action
• To keep any issues discussed in the meetings or written in the minutes confidential, unless otherwise agreed
• The TSC will also consider matters pertaining to the implementation study aspects of the study

8. ECONOMIC EVALUATION

An economic evaluation will be conducted alongside the DOORSTEP feasibility trial. This will be conducted in two parts. Initially a cost-effectiveness analysis will be conducted based on primary data collected within the trial. In addition, an economic model will be developed to explore the potential impact of the intervention on breast cancer detection and outcomes. Indicative estimates of cost-effectiveness will be generated. However, the key aim for the economic analysis in this feasibility study is to determine the plausibility of conducting an economic evaluation alongside a full trial, and to identify data gaps which would need to be addressed to facilitate this.

Data from the DOORSTEP trial will be used to generate an indicative estimate of the cost-effectiveness of offering free door to door transport for breast cancer screening compared with the standard invite to breast cancer screening. The incremental cost-effectiveness ratio (ICER) will be presented in terms of the cost per additional women screened. The primary analysis will be conducted from the perspective of the health care and personal social services provider; however, a secondary analysis will also include costs to patients – travel expenses and productivity losses. Costs associated with the provision of door-to-door transport will be collected as part of the trial monitoring. Travel costs incurred by patients and any impact on time out of work as a result of screening will be collected from the travel survey administered to all patients during the screening appointment.

A decision analytic model will be developed in consultation with clinical experts, patient representatives, and the screening service, to facilitate exploration of the potential impact of the intervention on breast cancer detection and outcomes. The model will be generated using best practice methods, with the model structure, health states and parameter values being derived from the published literature, data from the DOORSTEP trial and where necessary, expert clinical opinion (23). A cost-utility analysis will be conducted based on the model outputs, following the National Institute for Health and Care Excellence (NICE) reference case for health

technology appraisals (24). The outcome measure used in the model will be quality adjusted life years (QALYs) gained resulting from any increase in cancer detection as a result of screening. Results will be presented as expected ICERs which will be compared with the NICE cost-effectiveness threshold of £20,000-30,000 per QALY gained, and cost-effectiveness acceptability curves (CEAC) to demonstrate the probability of cost-effectiveness (25). Deterministic (one-way and scenario) and probabilistic (using Monte Carlo simulations) sensitivity analyses will be conducted to determine the impact of parameter value changes on estimates of cost-effectiveness and to establish the level of uncertainty surrounding the modelling results. A value of information analysis will also be conducted to estimate the value of conducting further research (26). This will allow research priorities to be established and for recommendations for data collection when progressing to a full trial.

The equity impact of the provision of free door to door transport for breast cancer screening will also be explored, for example using distributional analysis or equity informative cost-effectiveness analysis (depending on data available), to identify potential distributional impacts on costs and benefits by measures of deprivation (27). This will be informed by area level deprivation data in relation to the location of the GP practice, along with data collected by the NHS breast screening service and NHS England. Gaps in available data for the conduct of equity impact analysis will be identified and the feasibility of collecting data to inform equity analysis in a full trial will be monitored.

A full description of the analytical strategy will be provided in a separate health economics analysis plan prior to the start of analysis.

9. STATISTICAL ANALYSIS PLAN

9.1 FEASIBILITY OUTCOMES (PRIMARY OUTCOMES)

The feasibility outcomes, including recruitment figures, fidelity of intervention and outcome measure completion rates, will be reported and checked against the pre-specified progression criteria.

9.2 SCREENING UPTAKE

We will access routine breast screening anonymised data from the NHSBSP and NHS England for the included GP practices to assess the screening uptake rates and report results by key characteristics (e.g. ethnicity, area deprivation). The intraclass coefficient (ICC) calculated from this data and effect size of intended outcomes will be used to inform the sample size (power calculation) for the definitive RCT.

9.3 TRAVEL PROVIDERS

We will access anonymised data from the transport providers to calculate the number of women who booked transport to allow us to assess the intervention uptake rates, the cost of these journeys and to monitor possible contamination between arms.

9.4 TRAVEL SURVEY

All women (in both arms of the trial) will be asked to complete a travel survey when they attend their appointment to collect information on how they travelled to the screening appointment. There will be two travel surveys, one for the intervention arm and one for the control arm. Both travel surveys will explore information about how participants have travelled to the breast screening appointment (e.g. by car, taxi, walked), where they have travelled from (including their postcode so that we can calculated how far they travelled), an estimate of how long it took them to get to the appointment, whether they had any issues getting to their appointments, whether they travelled alone, how much it cost them to travel to their appointment and whether they had to miss work to attend their appointment. The travel survey will also collect information on whether they have previously attending a screening appointment. In addition, the travel survey will collect information about the participant including their GP practice, age group, ethnicity and whether English is their first language.

As part of this travel survey women in the intervention arm will be asked whether they would be interested in being interviewed. If interested in participating in the interviews they will be able to share details as part of the survey.

We have designed the travel survey so that it can be completed either:

- On paper and posted in a box at the screening location
- On paper and posted back in a free post envelope
- Electronically accessed using a website/ QR code
- Electronically using an iPad at the screening site

We have included the costs of purchasing vouchers for a prize draw for participants at each GP practice to incentivise returning the survey. The survey will be analysed using descriptive statistics and GIS software.

9.5 SAMPLE SIZE

The study sample size is estimated as 8000 women from eight GP practices. This is a pragmatic sample size based on the number of eligible women (between ages 50-70) at eight average sized

GP practices. This sample size will allow for the reliable estimation of key feasibility figures and detection of signal of efficacy for the future full trial (17).

9.6 PLANNED RECRUITMENT RATE

The trial plans to recruit GP practices whose women will be invited to attend a screening appointment in 2024. The end of the study will be defined as 3 months following the last breast screening invitation sent by the breast screening service.

10. QUALITATIVE ANALYSIS PLAN

To explore women's experiences and/or perceptions of the intervention, qualitative interviews will be conducted with them. In line with sample size recommendations for qualitative studies (20) we propose to interview approximately 30 women in the intervention arm (see Table 2). Approximately 20 women who attended their screening appointment (10 women who attended screening using the free transport service and 10 women who attended screening but preferred to use their own transport arrangement instead of the free transport service offered) will be identified and recruited by volunteering through the travel survey. Participants who are willing to take part in an interview will add their contact details (Phone number & email) to the travel survey. Twenty of the women who add their contact details will be invited by the research team for an interview. The research team will send the participants an invitation letter, relevant Participant Information Sheet (PIS) detailing the purpose of the study and what their participation would involve and a consent form. An Infographic Sheet will be attached to the study PIS. The date, time & venue (remote or in person) of the interview will be arranged based on the individual preference and convenience.

Women who did not attend their appointment (approximately 10) will be identified and contacted by HEY BSS. An identified contact person at the HEY BSS will help to identify potentially eligible participants and contact them to see whether they are willing to be contacted by the study team to be interviewed. Participants who are willing to participate in an interview will be asked to contact the research team. The research team will provide them with an invitation letter, relevant Participant Information Sheet (PIS) detailing the purpose of the study and what their participation would involve and a consent form. The date, time & venue (remote or in person) of the interview will be arranged by the individual preferences.

We will also interview 5 – 10 transport providers to explore their experiences/perceptions of providing free transport services to women attending the screening appointments. An identified

contact person at the transport company will help to identify potentially eligible participants and provide them with an invitation letter, relevant Participant Information Sheet (PIS) detailing the purpose of the study and what their participation would involve and a consent form. Participants who are willing to participate in an interview will be asked to contact the research team. The date, time & venue (remote or in person) of the interview will be arranged by the individual preferences.

All the participants will complete a consent form before starting an interview.

10.1 QUALITATIVE DATA COLLECTION

Semi-structured individual interviews will be conducted with eligible and consenting participants either face-to-face, online or by telephone depending on their preference and convenience. For participants who prefer to be interviewed online, they will be given the flexibility to choose a secured medium, which they are most familiar and comfortable with (for example, Zoom or Microsoft Teams). The interviews will last 30-60 minutes and will be audio recorded. The participants who take part in interview will receive a £20 gift voucher. To ensure equity, diversity and inclusion in this arm of the study, we will provide interpreter services for women who may require such services (e.g. who are unable to communicate in English language). Interviews will be navigated using topic guides developed from the study aims and objectives and wider literature. Open ended questions on the topic guides will consider women's perceptions of acceptability of the intervention and reasons for accepting or declining the intervention. Interviews for transport providers will include questions related to their experiences of transporting women to and from their breast screening appointment, including appointment booking (for transport) procedure and perceived sustainability of the free door to door initiative. To ensure data protection, we will transfer interview recordings to the University approved and encrypted storage system immediately after the interviews and delete them from the recorder. The interviews will be conducted between 2024 and early 2025.

10.2 QUALITATIVE DATA ANALYSIS

Interview recordings will be transcribed verbatim, and analysed using thematic analysis (22). This would involve a three-stage process of identifying, analysing and interpreting themes (patterns of meanings) within the data. After data familiarisation, descriptive codes will be generated using words which describe participants' views. These descriptive codes will be explored iteratively for patterns, similarities and differences, to develop themes. The themes will be reviewed in line with the research objectives and labelled accordingly. NVivo 12 software

(a qualitative data management software) will be used to manage the data analysis process. To ensure rigour, credibility and trustworthiness, data will be analysed by two researchers and conflicts resolved through discussion. A third researcher will be asked to mediate any unresolved conflict where necessary. Memos will also be kept to maintain an audit trail of the data analysis process.

11. QUALITY ASSURANCE

The trial will be conducted in accordance with the principles of Good Clinical Practice (GCP) in clinical trials, as applicable under UK regulations, the NHS Research Governance Framework (RGF) [and Scottish Executive Health Department Research Governance Framework for Health and Social Care 2006 (for studies conducted in Scotland)], and through adherence to HHTU Standard Operating Procedures (SOPs).

Investigators are required to promptly notify the HHTU of a serious breach (as defined in the latest version of the National Research Ethics Service (NRES) A 'serious breach' is defined as a breach of the protocol or of the conditions or principles of GCP (or equivalent standards for conduct of non-CTIMPs) which is likely to affect to a significant degree the safety or physical or mental integrity of the trial subjects, or the scientific value of the research.

In the event of doubt or for further information, the Investigator should contact the study Trial Manager at the HHTU.

12. ETHICAL CONSIDERATIONS

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland. Written Informed consent will be obtained from participants prior to commencing the interview. The right to decline study participation without giving a reason must be respected. The participant must remain free to withdraw at any time without giving a reason and without prejudicing his/her further treatment. The study will be submitted to and approved by a main REC, Confidentiality Advisory Group (CAG) and Research and Innovation Development Advisory Committee (RIDAC). The HHTU will provide the main REC, CAG and RIDAC with a copy of the final protocol, participant information sheets, consent forms and all other relevant study documentation.

13. CONFIDENTIALITY

Full details will be available in the Study Data Management Plan, Data Protection Impact Assessment (DPIA) and Privacy Notice. The HHTU data management team will be responsible for insuring compliance with General Data Protection Regulation 2018.

All site investigators and research staff must comply with the requirements of the General Data Protection Regulation 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Regulation's core principles.

HHTU and sponsor will maintain the confidentiality of all participant data in accordance with General Data Protection Regulation Act (2018) and will not reproduce or disclose any information by which participants could be identified. Confidentiality will be maintained at all times.

Access to personal data for this project will be limited to named individuals who will accept terms of use ahead of being granted individual user-based access. HHTU data systems have a full audit trail which cannot be edited by HHTU staff. Personal data for this specific project will be limited to participants names and their contact details for the purpose of interview or participating into a prize draw.

Participants will be informed that their personal data will be entered into the cloud-based EDC. Study data will be pseudo anonymised and related forms will be identified using the study ID only. Participant names and contact details will be held in a restricted folder within the same system, to enable the central researcher to undertake an interview. All hard copy data will be stored at study sites in a locked filing cabinet in accordance with data protection requirements for the retention of research data policies.

13.1 FINANCIAL AND OTHER COMPETING INTERESTS FOR THE CHIEF INVESTIGATOR, PIS AT EACH SITE AND COMMITTEE MEMBERS FOR THE OVERALL TRIAL MANAGEMENT

Any competing interests that might influence study design, conduct, or reporting will be identified, disclosed and documented in the eTMF. The oversight groups will determine what it is appropriate to report; details will be in the Dissemination and Publication Plan.

Disclosure should reflect:

- ownership interests that may be related to products, services, or interventions considered for use in the study or that may be significantly affected by the study

- commercial ties requiring disclosure include, but are not restricted to, any pharmaceutical, behaviour modification, and/or technology company
- any non-commercial potential conflicts e.g. professional collaborations that may impact on academic promotion

13.2 ARCHIVING

Archiving will be authorised by the sponsor following submission of the end of study report. All essential study documents including source documents will be archived in accordance with the HHTU Data and Study Document Archiving SOP. Plan for a minimum period of 10 years after study completion. Destruction of essential documents will require authorisation from the sponsor.

14. PUBLIC AND PATIENT INVOLVEMENT

We have set up a Public Advisory Group made up of 4 women of breast screening age which will meet at regular points throughout the trial. The group have helped us to develop the travel survey and the interview topic guide, and ensure that the letter to women about the transport offer, and the participant information sheet and consent form for the interviews, are written in Plain English. We have discussed accessing NHS BSS data with the group, and the cost effectiveness evaluation. We will share our initial findings with them for sense checking, and seek their help and advice to disseminate our findings to public audiences. We will involve them in evaluating the trial and helping to plan the next stage of the research. We have also recruited one woman of breast screening age to join the Trial Management Group, and two women to sit on the Trial Steering Committee.

14.1 PATIENT BENEFIT

A summary of the patient benefits is provided in Figure 2, which indicates the short to longer term impacts of the trial. Women registered at GP practices in the intervention arm will directly benefit from the offer of free door-to-door transport to get to and from their breast screening appointments. We expect at least one additional woman to receive a breast cancer diagnosis following attending a screening appointment within the feasibility trial.

This trial will allow us to assess the feasibility of conducting a large-scale, definitive, Phase III GP RCT. We will assess if there is a signal of efficacy, estimate cost effectiveness and data will inform sample size calculations for the future trial. The future benefits include the submission of a

funding application in Year 3 for the future definitive trial targeting Yorkshire. There is also potential to expand and apply the findings from this study to other cancer screening programmes where people have to travel to the screening provider (e.g. cervical, lung, prostate, colorectal).

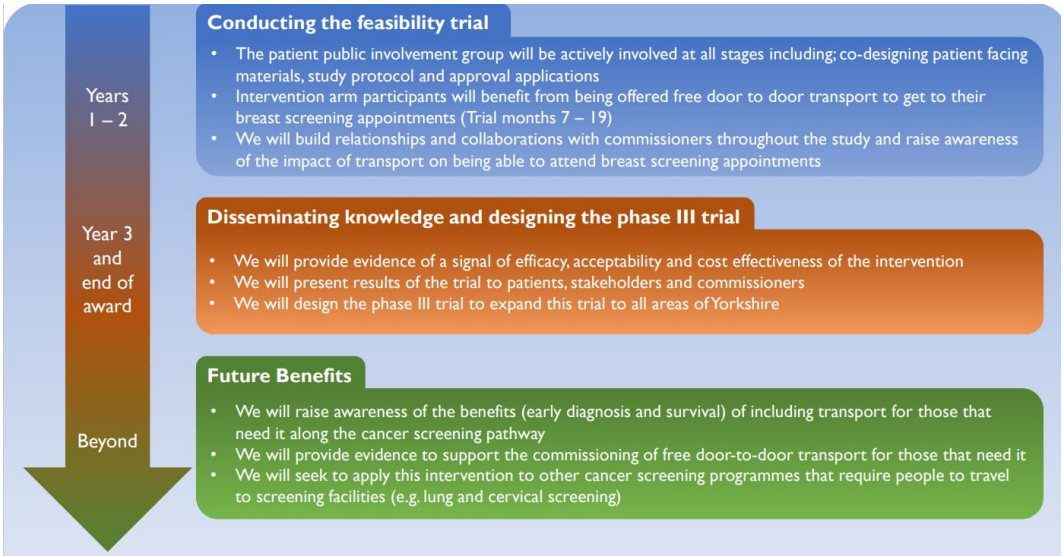

Figure 2 Benefit to patients from this study

15. STATEMENT OF INDEMNITY

The University of Hull has an insurance policy that includes cover for no-fault compensation in respect of accidental injury to a research participant, only if caused by the University.

16. STUDY ORGANISATIONAL STRUCTURE

Chief Investigator (CI) – The CI will have overall responsibility for the trial design, set-up, conduct, co-ordination and management

Trial Sponsor – The Sponsor will be responsible for trial initiation management and financing of the trial as defined by Directive 2001/20/EC. These responsibilities are delegated to the HHTU as detailed in the trial contract.

Clinical Trials Research Unit – The HHTU will have responsibility for trial conduct as delegated by the Sponsor in accordance with GCP standards. The HHTU will conduct trial set-up and data monitoring in line with HHTU SOPs and partner SOPs (if applicable). Responsibilities include: trial administration, protocol development, trial design, main REC/MHRA/ HRA regulatory

submissions, data management, safety reporting, randomisation design and service, database development and provision, database administrative functions, source data verification, data monitoring, statistical analyses, HHTU and site training, trial reports and results dissemination.

Research Fellow - This will vary and the role should be specified on a trial-specific basis.

Trial Qualitative lead. The qualitative team will be responsible for recruiting individuals for the interviews and conducting, analysing and reporting the results.

Trial Statistician. The trial statistician will have responsibility for designing and undertaking the statistical analysis of the screening uptake data and travel surveys and reporting the results.

Trial Patient Public Involvement coordinator. The PPI coordinator will have responsibility for convening the patient advisory group meetings and reporting back to the patient advisory group.

Trial Health Economists. The trial economists will have responsibility for undertaking the health economics analysis and reporting the results.

Trial Management Group (TMG) - A TMG Terms of Reference document will be developed and approved at the first meeting. The TMG will be responsible for over sight of study set-up, study management, study data collection, data quality and analysis and publishing study result.

Trial Steering Committee (TSC) – A TSC will provide overall supervision of the conduct of the trial.

17. PUBLICATION POLICY

Prior to trial recruitment, the trial will be registered with an authorised registry, according to the International Committee of Medical Journal Editors (ICMJE) Guidelines.

The success of the trial depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated on the trial, through authorship and contributions. Authorship guidelines will be provided for manuscripts submitted to medical journals. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- and final approval of the version to be published
- and that all these conditions must be met (**www.icmje.org**)

The CI, Research Fellows, and relevant senior HHTU staff will be named as authors in all publications. All collaborators will be listed as contributors for the main trial publication, alongside roles in trial planning, conducting and reporting. To maintain trial scientific integrity, data will not be released before the first publication of primary endpoint analysis, either for publication or oral presentation, without TSC permission. Individual collaborators must not publish data concerning their participants before the first publication of primary endpoint analysis.

17.1DISSEMINATION POLICY

Publications for the study will meet the standards required for submission to high quality peer reviewed journals and the main trial papers will be reported in accordance with the CONSORT guidance. **http://www.consort-statement.org/.** On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared.

The results will be disseminated in peer reviewed journals, through local and other relevant clinical networks and at national and international meetings. Participants will be sent a summary of the findings, if requested and a copy of the final accepted manuscript of the primary paper after the results have been published.

The funding source (Yorkshire Cancer Research) will be acknowledged within all publications, and a copy sent for their prior information according to their requirements. The Funder does not have publication rights of the data from the study.

The study protocol manuscript will be prepared and published. The protocol will be available on the CI and HHTU website, and the study design synopsis available on the ISRCTN website.

17.2AUTHORSHIP ELIGIBILITY GUIDELINES AND ANY INTENDED USE OF PROFESSIONAL WRITERS

All publications and presentations relating to the study are required to be authorised by the Study Steering Group (SSG), who will prepare the Study Dissemination and Publications Plan.

The agreement will include:

- guidelines on authorship on the final trial report consistent with the Vancouver Recommendations from The International Committee of Medical Journal Editors
- whether participating investigators have rights to publish any of the study data
- any time limits or review requirements on the publications

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